

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

CX 4/40.2

CL 2004/48 - PR
September 2004

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary,
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **REQUEST FOR COMMENTS ON THE MATERIALS FOR REVIEW IN
SUPPORT OF ESTABLISHMENT OF CODEX INTERIM MRLs FOR
SAFER REPLACEMENT PESTICIDES**

DEADLINE: **15 January 2005**

COMMENTS: **To:** Dr Stephen FUNK
Health Effects Division
Office of Pesticide Programs (H7509C)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Tel: +1 703 305-5430
Fax: +1 703 305-0871
E-mail: Funk.Steve@epa.gov

Copy to: Secretary
Codex Alimentarius Commission
FAO
Viale delle Terme di Caracalla
00100 Rome, Italy
Fax: +39 06 5705 4593
E-mail: codex@fao.org

BACKGROUND

Guidance for Review of Materials

Soon you will receive detailed information packages for the three chemicals that were nominated for review in the Pilot Project for the Examination of National MRLs as Interim CODEX MRLs for Safer Replacement Pesticides. The following is suggested guidance for reviewing these materials.

Schedule

The schedule agreed upon at the 36th Session of the CCPR for review and consideration of these interim

MRLs and the interim MRL process is outlined below (ALINORM 04/27/04, paragraphs 220-234):

Distribute detailed packages via Codex Secretariat/CCPR solicits comments from member countries and JMPR	Spring/Summer 2004
Member Countries complete review, return comments to the Pilot Project Workgroup via the Codex Secretariat and with copies to the Chairman of the CCPR	January 15, 2005
The Pilot Project Workgroup with assistance from the Codex Secretariat, collates comments (and notes any technical issues). Comments distributed via Codex Contact Points to member countries	March 1, 2005
Working Group on Priorities analyzes comments from member countries and JMPR/prepares a preliminary appraisal of technical issues for consideration at the 2005 CCPR	Mid-March 2005
2005 Working Group on Priorities will address and seek to resolve technical issues and make recommendations to the CCPR on advancement or deletion of proposed interim MRLs. It will also seek to resolve issues related to the process and make recommendations on process improvements. Pilot Project Working Group prepares draft proposal on refinements to the procedure based on comment record.	2005 Working Group on Priorities
CCPR decides on the proposed interim MRLs; considers recommendations on the process and decides whether to continue with development of interim MRLs and determines any necessary revisions to the process.	37th Session of CCPR

Please note that the packages^a for bifenazate and trifloxystrobin are complete, according to the decisions made at the 36th session of the CCPR. These packages include proposed MRLs for all of the commodities that were originally proposed by the manufacturer. The interim MRLs proposed for bifenazate are based on MRLs established in the US and in Japan and the interim MRLs proposed for trifloxystrobin are based on MRLs established in the US and the EU. The US was able to obtain supporting documentation from the relevant national governments—the US, Japan, and the EU.

The package for fludioxonil proposes interim MRLs only for those MRLs proposed by the manufacturer that are supported by MRLs established in the US. This change was made because the EU is currently reviewing fludioxonil. Because of this it was decided that it would be difficult to obtain the individual national government assessments and, in any case, these would shortly be replaced by the MRLs determined by the EU evaluations.

The interim MRLs originally proposed by the manufacture for fludioxonil which were not included in this package might be considered by the 2006 CCPR, after the evaluation of fludioxonil by the EU.

^a All packages will be available only in English.

Due to the very large size, the information packages are being distributed to the Codex Contact Points in CD Rom. For hard or additional copies of CD Rom please contact the following person:

Kathy Monk
Office of Pesticide Programms
US EPA
1200 Pennsylvania Ave NW, 7505C
Washington, DC 20460
USA
Email: Monk.Kathy@EPA.gov
Phone: 1-703-308-8071

Guide to Package Information

These three packages include all of the various types of information that have been requested during the development of this pilot project. The packages are quite large and contain duplicative information. However, all of the information is included because:

- One of the purposes of this pilot process is to decide what information is really needed (and in what format).
- For the pilot we thought it prudent to provide everything that has been requested because we wanted all reviewers to have the information which they think is necessary.

Each of the three packages contains the following information:

I. Summary (written by the US Delegation)

- a. Introduction
- b. Reduced Risk
- c. Toxicology/Hazard
- d. Residue Chemistry
- e. Proposed Interim MRLs
- f. Dietary Risk Assessment
 - US EPA
 - Other National Governments
 - JMPR-Type (performed by the USEPA for this project)

II. National Government Assessments

- a. US EPA
 - Regulatory Documents/Risk Assessments
 - Toxicology/Endpoint Selection
 - Residue Chemistry Analysis
 - Dietary/Exposure Risk Assessments

b. Other National Governments

III. Toxicology Study Results [Data Evaluation Records (DERs) prepared by the USEPA]

IV. Residue Chemistry Study Results [Data Evaluation Records (DERs) prepared by the USEPA].

V. References (by MRID number) for III and IV.

VI. Toxicology and Residue Chemistry Study Results from Other National Governments (trifloxystrobin only).

VII. Information and Data from the Manufacturer, including manufacturer's list of proposed interim MRLs and nine additional items specified in CX/PR 03/14 (Agenda Item 11, 35th CCPR) and ALINORM 03/24A, paragraphs 176 – 186.

In Section I the US, as the nominating country, has written a summary of what we believe is the most pertinent information. We have confirmed the accuracy of the information contained in the summary.

In Section II we have included the relevant national government assessments. In the case of the US EPA this includes risk assessment documents as well as the hazard and exposure assessment documents (such as endpoint selection committee reports and analyses of the residue chemistry results). For bifenazate/tea, we have provided only the JMPR-type analysis which was provided by the company to Japan and which formed the basis of the Japanese analysis and establishment of MRLs. The US has verified with the Japanese government that this information is correct and formed the basis of the Japanese establishment of an MRL for residues of bifenazate on tea.

Sections III and IV contain the USEPA summaries and reviews of the relevant toxicology and residue chemistry data supporting the establishment of the chemical's MRLs in the US.

Section V is a list of references (by MRID number) for the toxicology and residue chemistry studies of Sections III and IV. The US, as the nominating country, has also agreed that if any member country requests a specific study (raw data) as a critical part of their review of the nomination, the US would facilitate resolving the issue with the manufacturer. Please address these requests to Kathy Monk at monk.kathy@epa.gov

In the case of trifloxystrobin only, Section VI contains sections of the evaluations of the EU.

The final section (VI for fludioxonil and bifenazate, VII for trifloxystrobin) contains the summaries that CCPR had previously asked the manufacturers to prepare (CX/PR03/14, 2003 CCPR). These summaries contain the following information: the nomination form; summary toxicology information; proposed interim MRLs; summary residue information used as a basis for the MRLs; summary GAP information; residue definitions; summary description of the enforcement analytical method(s); dietary intake exposure analyses, per the national government(s); dietary intake exposure analyses, per the JMPR methodology; and rationale for a safer replacement designation). Much of this is now repetitive as the result of the specific information that the nominating government has been asked to provide and verify (study results and national government analyses and assessments).

Suggested Format for Comments

Please provide your comments in the following format, using the Table provided below to provide the information requested in Sections I-III below by **15 January 2005**. A narrative format should be used for Sections IV-VI.

- I. Make a statement concerning whether you support the proposed interim MRLs.
- II. If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain your position.
- III. If you oppose establishment of an interim MRL due to lack of information, please describe what information would have been necessary for you to make a decision.
- IV. Please comment on what specific information/documents you believe would be necessary in the future to establish interim MRLs. Also comment on the most appropriate format of the information and who should supply and verify it.
- V. Please comment on any process improvements you would like to see that would allow for the successful continuation of this process.
- VI. Provide other comments.

Comments on Proposed Interim MRLs (Sections I-III Above)

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Bifenazate				
Apple pomace, wet/2.0				
Cottonseed/ SO 0691/1.0				
Pome fruits/ FP 0009/1.0				
Grapes/FB 0269/1.0				
Dried grapes/DF0269/2.0				
Hops/DH 1100/15.0				
Nectarine/ FS 0245/2.0				
Tree nuts/ TN 0085/ 0.2				
Peach/ FS 0247/2.0				
Mint top/ HH 0738/ 25.0				
Plums/ FS 0014/0.3				
Strawberry/ FB0275/2.0				
Cucumber/ VC 0424/ 0.5				

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Squash/ VC 0431/0.7				
Melons/ VC 0046/0.3				
Watermelon/ VC 0432/ 0.3				
Pepper/ VO 0051/2.0				
Chili pepper/ VO 0444/2.0				
Okra/ VO 0442/2.0				
Tomato/ VO 0448/1.0				
Eggplant/ VO 0440/ 2.0				
Meat (from mammals other than marine animals)/ MM 095/0.1 (fat)				
Edible offal, mammalian/MO 0105/ 0.02				
Milks/ML 0106/0.01				
Poultry meat/ PM 110/ 0.01(*)				
Poultry, edible offal of/PO110/ 0.01(*)				
Eggs/PE112/ 0.01(*)				

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Tea/DT 1114/2.0				
Trifloxystrobin				
Meat (from mammals other than marine)/ MM 95/0.04(*)				
Edible offal (mammalian)/MO 105 /0.05				
Eggs/PE 112/0.04(*)				
Pome fruits/ FP 9/1.0				
Grapes/ FB 269/ 3.0				
Grapes, dried/ DF269/5.0				
Milks/ML 106/0.02(*)				
Poultry meat/PM 110/0.04(*)				
Poultry, edible offal of/PO 111/ 0.04(*)				
Barley/GC 640/0.3				
Fludioxonil				
Stone fruit/FS 14/ 5.0				
Grapes/FB 269/2.0				

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Strawberry/ FB 275/2.0				
Raspberry/ FB 272/5.0				
Blackberry/ FB264/5.0				
Blueberry/FB 20/2.0				
Currants/FB 21/2.0				
Lychee/FI 343/1.0				
Logan/FI 342/1.0				
Pulasan/FI 357/1.0				
Rambutan/FI 358/1.0				
Spanish lime/FI 366/1.0				
Onion/VA 358/0.2				
Cabbages, head/VB 41/2.0				
Broccoli/ VB 400/2.0				
Potato/VR 589/0.02(*)				
Carrot/VR 577/1.0				
Watercress/ VL 473/10.0				

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Mustard greens/VL 485/20.0				
Herbs (fresh)/HH 726/10.0				
Herbs (dry)/HH 726/65.0				
Rapeseed/SO 495/0.01(*)				
Cottonseed/ SO 691/0.05(*)				
Sunflower seed/SO 702/0.01(*)				
Soya/SO 4723/0.01(*)				
Pistachio/TN 675/0.1				
Wheat/GC 645/0.02(*)				
Rye/GC 650/0.02(*)				
Spelt/GC 4673/0.02(*)				
Triticale/GC 653/0.02(*)				
Barley/GC 640/0.02(*)				
Oats/GC 647/0.02(*)				
Maize/GC 645/0.02(*)				

Commodity/ Codex Classification/ Proposed Interim MRL (mg/kg)	Support Estab of Interim MRL? Y = Yes N = No	If you oppose an interim MRL as the result of your review of the information provided or believe that a different interim MRL is appropriate, please explain.	If you oppose establishment of an interim MRL due to lack of information, please describe what information would be necessary for you to make a decision	Other Comments
Sweet corn (corn-on- the-cob)/VO 1275/0.02(*)				
Popcorn/GC 656/0.02(*)				
Sorghum/GC 651/0.02(*)				
Meat (from mammals other than marine)/MM95/0.01(*)				
Edible offal (mammalian)/MO 105/ 0.05(*)				
Milks/ML 106/0.01(*)				
Poultry meat/PM 110/0.01(*)				
Poultry, edible offal of/PO 111/ 0.05(*)				
Eggs/PE 112/0.05(*)				